or with the frequency prescribed, recommended, or suggested in the directions borne on the label, "One capsule every 2 or 3 hours with a glassful or more of water"; (2) in that the statement "For Temporary Relief of Minor Colds, Flu," borne on the label, was false and misleading since the article would not be efficacious as a temporary relief of minor colds and flu; (3) in that the article was fabricated from two or more ingredients and contained the alkaloids of atropine, hyoscine, and hyoscyamine, as constituents of belladonna, and its label did not bear the name and quantity or proportion of the said alkaloids or, in lieu thereof, the quantity or proportion of total alkaloids contained in the article as constituents of belladonna; (4) in that its labeling failed to bear adequate directions for use since the directions on the label provided for the administration of excessive amounts of acetanilid; and (5) in that its labeling failed to bear adequate warnings against use or against unsafe dosage or duration of administration, since its labeling did not bear warning that it might cause serious blood disturbances, anemia, collapse, or dependence on the drug; that it should not be used frequently or continuously; that it should be used cautiously if dryness of the throat occurred; that its use should be discontinued if rapid pulse or blurring of vision occurred; and that continued use of the article, which was a laxative, might result in the dependence of the user upon laxatives to move the bowels.

Analysis of Nelson's Antacid Powder disclosed that the article consisted essentially of compounds of sodium, calcium, magnesium, and carbonate, and that it contained no bismuth salts.

The article was alleged to be adulterated in that its strength differed from that which it purported to possess since it purported to contain bismuth salts, whereas it contained no bismuth salts. It was alleged to be misbranded in that the statement "Bismuth Salts in the form of Carbonates Subnitrates," borne on the label, was false and misleading. It was alleged to be misbranded further because of false and misleading statements in its labeling which represented and suggested that the article would be efficacious in the treatment of gastric ulcers, gastralgia, gastritis, and acidosis; that it would form a soothing, protecting coating over the highly inflamed mucous membranes of the stomach; that it was mildly astringent and sedative; that it would convert all protein foods such as meats and albumens into soluble and readily absorbed peptones; that it would convert all starchy foods into soluble dextrins and sugars; that it would be efficacious in treatment of functional stomach disorders and indigestion; that it was a strictly scientific preparation which offered a rational and effective method of reestablishing the normal alkalinity of the body fluids without danger of systemic disturbance; that it would instantly neutralize all stomach acids; and that it would be efficacious as an instant relief from acidity and gas pressure. It was alleged to be further misbranded in that its label failed to bear an accurate statement of the quantity of contents.

On October 25, 1943, pleas of guilty having been entered, the court imposed a fine of $150 on each of 3 counts, a total fine of $450 plus costs, against each defendant. Payment of the fine and costs against the corporate defendant was suspended.

1202. Misbranding of Grover Graham Remedy. U. S. v. 22 Bottles and 22 Bottles of Grover Graham Remedy (and 4 other seizure actions against the same product). Default decrees of condemnation and destruction. (F. D. C. Nos. 11750, 11816, 11867, 11868, 11977. Sample Nos. 47774–F, 50750–F, 51636–F, 65932–F, 76308–F.)

Between February 5 and March 10, 1944, the United States attorneys for the Eastern District of Missouri, the District of New Jersey, the District of Massachusetts, and the Middle District of Pennsylvania filed libels against the following quantities of the above-named product, contained in 6-ounce and 12-ounce size bottles: 44 bottles at St. Louis, Mo., 65 bottles at Newark, N. J., 60 bottles at Boston, Mass., 82 bottles at Hackensack, N. J., and 18 bottles at Northumberland, Pa., alleging that the article had been shipped on or about December 6 and 21, 1943, and January 24, 1944, from Newburgh, N. Y., by the Grover Graham Co., Inc.; and charging that it was misbranded.

Examination of samples disclosed that the article consisted essentially of magnesia, sodium bicarbonate, sodium bromide, equivalent to 8¼ grains or 8.4 grains per tablespoonful, alcohol, chloroform, oil of peppermint, and coloring matter.

The article was alleged to be misbranded in that the statements on its label which represented and suggested that it would be efficacious in the treatment

of indigestion, dyspepsia, symptoms of indigestion, and other ailments due to imperfect or retarded functioning of the digestive organs, and that the article could be taken with perfect safety, were false and misleading since the article was not an adequate treatment for the conditions, ailments, and symptoms mentioned; and it could not be taken with perfect safety inasmuch as it contained a material proportion of sodium bromide.

The article was alleged to be further misbranded (1) in that its labels did not bear adequate directions for use since the directions appearing thereon, "Directions * * * Take a large tablespoonful after meals three times a day or whenever symptoms of indigestion occur. * * * Dose should be half a wineglassful followed by another dose in a half hour if necessary. The Remedy may be taken with perfect safety as often as necessary," provided for an excessive amount of sodium bromide and placed no limitation on the number of doses to be taken daily; (2) in that its labeling failed to bear any warnings that frequent or continued use of the article might lead to mental derangement, skin eruptions, or other serious effects, and that the article should not be taken by those suffering from kidney disease; and (3) in that it was dangerous to health when used in the dosage, or with the frequency prescribed, recommended, or suggested in the labeling, "Dose should be half a wineglassful followed by another dose in a half hour if necessary. The remedy may be taken with perfect safety as often as necessary."

The article, with the exception of that in the Newark lot, was alleged to be further misbranded in that the statement of the quantity or proportion of sodium bromide contained in the article did not appear on its label in such terms as to render it likely to be understood by the ordinary individual, since the statement on the label read "Sodium Bromide U. S. P. 3½%," whereas, in order to be understood by the ordinary individual, the sodium bromide contained in the article should have been declared in terms of grains per tablespoonful.

Between March 7 and September 6, 1944, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

PRODUCTS REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

1203. Misbranding of Dimels. U. S. v. 68 Bottles and 1 Bottle of Capsules Dimels. Decree of condemnation and destruction. (F. D. C. No. 9914. Sample No. 3345–F.)

On or about May 12, 1943, the United States attorney for the Western District of Missouri filed a libel against 68 100-capsule bottles and 1 500-capsule bottle of the above-named product at Kansas City, Mo., alleging that the article had been shipped on or about March 11, 1943, from McKeesport, Pa., by Jones-Hague, Inc.; and charging that it was misbranded.

Examination disclosed that each capsule contained approximately 5 grains of a mixture of dried, powdered animal material and kaolin (China clay). The animal material was apparently of a glandular nature such as pancreas. It contained a small proportion of insulin and a starch-splitting enzyme equivalent to ½ percent pancreatin.

The article was alleged to be misbranded (1) in that it was a drug composed partly of insulin that was not from a batch for which a certificate or release had been issued pursuant to the law; (2) in that the statement on the label, "Each capsule contains Hormone Complexes as found in Isles Langerhans * * * Dosage—One capsule three times daily," was misleading in the absence of a statement of the material fact that, when consumed in accordance with the directions on the label, the article would not produce the well-known effects of the hormones found in the islands of Langerhans; and (3) in that the statements on the label, "To be taken only upon advice of physician. Its use otherwise may be dangerous. To be used only in uncomplicated and incipient Diabetes," were false and misleading since the article, if taken otherwise than upon advice of a physician, would not be dangerous, and it would be useless in the treatment of diabetes.

On January 11, 1944, Jones-Hague, Inc., having previously filed an answer denying the allegations of the libel and a brief in support of such answer, but having failed to make any further appearance in the proceedings, judgment of condemnation was entered and the product was ordered destroyed.